REMARKS

1. Examiner rejected claims 1-4, 20, 24 and 32 under 35 USC 102(b) as being anticipated by Shahidi (US 6,167,296).

2. Applicant respectfully disagrees with Examiner's assertion that claims 1-4, 20, 24 and 32 are anticipated by Shahidi. Applicant submits that it is not possible to use Shahidi in Sclemm's Canal as recited in the claims of the present application. The reasons are primarily related to the small scale of Schlemm's canal, the deformability of the eye as compared to neurosurgical or orthopedic applications involving bone, and the need to advance a microcannula *into and along* a tissue passageway such as Schlemm's Canal.

> Shahidi "provides an improved system and method for displaying 3D images of anatomical structures in real time during surgery to enable the surgeon to navigate through these structures during the performance of surgical procedures. This system is also useful in planning of surgical procedures. The system includes a computer with a display and input devices such as a keyboard and mouse. The system includes a position tracking system that is connected both to the computer and also to the surgical probes or other instruments that are used by the surgeon. The position tracking system provides continual real time data to the computer indicating the location and orientation of the surgical instrument in use. The computer further includes a memory containing patient data produced by imaging scans, such as CT or MRI scans, from which 2-dimensional and 3-dimensional images of the anatomical structure may be generated. Means are provided for registration of these images with respect to the patient." (Column 3, lines 22-39)
>
> "In addition, for probes or instruments being used that are capable themselves of generating images, such as ultrasound probes, endoscopes, or surgical microscopes, the system provides means for integrating these images with those generated from the scan data. The software enables the user to overlay the 'actual images' generated by these instruments with the 'virtual images' generated from the scan data." (Column 4, lines 6-13)

In Shahidi, the use of stored patient image data to provide surgical guidance in real time relies upon the stored image data remaining accurate during surgery. For surgical targets involving hard tissues such as bone and cartilage, this method has obvious applicability, for example in neurosurgery or orthopedic surgery. However, the eye is a relatively soft

structure, whose size and shape relates to the intraocular pressure and forces being applied directly during surgery. Variations in the patient's intraocular pressure, the use of a protective paracentesis to remove intraocular pressure during eye surgery, and the force applied to the eye by the imaging means or the microsurgical device can change the size and shape of the anterior segment angle containing Schlemm's Canal by several millimeters. Since Schlemm's Canal is a tissue structure of approximately 150 microns in diameter, such lack of accuracy of potentially thousands of microns from the stored image data would be ineffective in guiding a microcannula to Schlemm's Canal by the method of Shahidi.

The microcannula of Applicant's claimed invention is sized to access Schlemm's Canal. Such small dimensions limit the use of the microcannula to generate images to integrate with stored scan data as described in Shahidi. Images from a 150 micron diameter cannula would be limited in depth and breadth due to the restricted size for the imaging components, such as aperture size. While viewing reconstructed images from the perspective of a surgical instrument may be useful for avoiding certain tissues in the path of the surgical instrument, it is of limited utility in guiding a small device to a small target. If the view from the instrument is off target, the image provided by imaging means in the instrument or microcannula would simply be of the off target tissues. The scope of imaging from a small microcannula is too restricted to allow it to readily find the correct target, unless it happens by chance to be in it's imaging path. The best method to guide a surgical instrument to a tissue target is to image the tissue target in reference to the instrument from a position able to view both the target and the instrument, not from the point of view of the surgical instrument.

Further, means for registration of images as required by Shahidi are possible when involving hard tissues by using fiducials (Column 5, lines 33-37) affixed to bone or cartilage. Whereas, with the large deformability of the tissues of the eye relative to the dimensions of the tissue target of the present invention, Schlemm's Canal, the Shahidi image registration method would seem to be of no practical use, since the method of Shahidi would not provide data reliable enough for use in guiding a surgical instrument to Schlemm's Canal of the eye.

Further, Shahidi allows guidance of the trajectory of the surgical instrument toward the target tissues and the imaging of tissue structures in the path of the surgical instrument. In the presently claimed invention, it is not sufficient to simply guide the tip of the surgical instrument to the target tissues, instead it is desired to guide the instrument into and along the lumen of Schlemm's Canal. There is no apparent way Shahidi could be used to guide a surgical instrument into a deformable soft tissue structure such as Schlemm's Canal.

In conclusion, Shahidi does not disclose a device that could be used to locate and advance a microsurgical device into Schlemm's Canal as recited in claims 1-4, 20, 24 and 32. Therefore, Applicant respectfully requests that the rejection under 102(e) be withdrawn.

3. Examiner rejected claim 6 and 7 under 35 USC 103(a) as being unpatentable over Shahidi in view of Jones (3,941,122).

4. Applicant respectfully disagrees with Examiner's rejection. Jones is designed

> "to provide a new and improved process and apparatus for employing high-frequency ultrasound acoustic wave energy at very high density, preferably intermittently, to dissolve materials, particularly semi-solid and solid materials, which process and apparatus shall not be subject to the above-recounted and other disadvantages and problems of prior techniques, but that, to the contrary, produce highly controllable, selective and localized tissue reduction results and without damage to surrounding material." (Column 5, lines 33-43)
>
> "A further object is to provide such a novel process and apparatus that is particularly adapted and safe for ophthalmic procedures and for other procedures on the human or animal body and with the above novel results." (Column 5, lines 44-48)

The high frequency ultrasound recited in claims 6 and 7 provide high resolution imaging to allow examination of Schlemm's Canal of the eye for surgical guidance. The high frequency ultrasound of Jones is used to dissolve tissues. If the invention of Jones was used to provide ultrasound imaging for surgical guidance, the tissue being imaged would be dissolved. Besides the undesired and unnecessary damage to the eye, the ultrasound invention of Jones

is not described to provide imaging information for surgical guidance. Ultrasound characteristics for affecting tissues is much different than ultrasound characteristics for medical imaging.

Further, the use of the high frequency ultrasound such as described in Jones would not overcome the intrinsic deficiencies of Shahidi to function with soft, deformable tissues, as argued above with respect to claim 1, from which claims 6 and 7 depend.

Therefore, Applicant submits that the combination Shahidi and Jones does not disclose or suggest an ultrasound device for examination of the sclera within the 10 and 40 MHz ranges as recited in claims 6 and 7. Applicant respectfully requests that this rejection be withdrawn.

5. Examiner rejected claim 8 under 35 USC 103(a) as being unpatentable over Shahidi in view of Bernstein (6,132,699).

6. Applicant respectfully disagrees with Examiner's rejection. Bernstein et al. describes methods

> "for the synthesis of polymeric delivery systems consisting of synthetic polymeric microparticles which contain fluorinated gases, especially perfluorocarbons. The microparticles are useful in a variety of diagnostic ultrasound imaging applications, particularly in ultrasound procedures such as blood vessel imaging and echocardiography. The incorporation of a fluorinated gas significantly increases the echogenicity as compared with the same synthetic polymeric microparticles incorporating air." (Column 5, lines 9-18)

While Bernstein et al. describes the use of contrast agents for ultrasound imaging, it does not describe the use of contrast agents for image guided surgery or suggest any rationale for use in such applications. The use of a contrast agent such as described in Bernstein et al. would not overcome the intrinsic deficiencies of Shahidi to function with soft, deformable tissues, as argued above with respect to claim 1, from which claim 8 depends.

Therefore, Applicant submits that the combination Shahidi and Bernstein et al. does not disclose or suggest the features recited in claim 8. Applicant respectfully requests that this rejection be withdrawn.

7. Examiner rejected claim 10 under 35 USC 103(a) as being unpatentable over Shahidi in view of LeBlanc et al. (5,989,189).

8. Applicant respectfully disagrees with Examiner's rejection. LeBlanc et al. describes

> "a system for producing visual representations of eye structures that includes an ultrasound transducer, a processor, and a display device. The ultrasonic transducer transmits ultrasound signals into eye structures, receives ultrasound signals reflected by the eye structures, and sends electronic signals representative of the received ultrasound signals to the processor. The processor translates the electronic signals into image data representing a non-background portion of an image for display by the display device by correlating each value of a parameter of the electronic signals (e.g. each value of echo signal intensity) with one of a plurality of multichromatic color hues in accordance with a continuous gradation of the multichromatic color hues that forms the entirety of the non-background portion of the image." (Column 2, lines 32-46)

The use of ultrasound to image the larger structures of the eye are well known in ophthalmic imaging. The eye structures described by LeBlanc et al. such as the cornea, retina, sclera, are large structures with dimensions on the order of thousands of microns. Schlemm's Canal of the eye is a small vein-like structure approximately 150 micron in diameter. LeBlanc et al. does not describe or suggest the use of high frequency ultrasound necessary for resolution of small tissue spaces such as Schlemm's Canal by ultrasound imaging or the use of a plurality of multichromatic color hues to image Schlemm's Canal, or any applicability to imaging Schlemm's Canal. Therefore a combination of LeBlanc et al. and Shahidi would still not disclose or suggest the device recited in claim 10. Further, the use of the LeBlanc et al. imaging would not overcome the intrinsic deficiencies of Shahidi to function with soft, deformable tissues, as argued above with respect to claim 1, from which claim 10 depends.

Further, the invention of LeBlanc et al. does not appear to be applicable for use in image guided surgery of the eye. In the detailed description of the invention in column 5, the invention is described in Figure 1, "In operation of the system, a physician places the ultrasonic transducer 12 near a patient's closed eye, and the ultrasonic transducer 12 emits ultrasound waves into the eye and receives echo signals from the emitted ultrasound waves." Imaging through the eyelid would provide little or no useful imaging results for locating Schlemm's Canal. In addition, if the imaging is used to guide a surgical instrument, such use would involve the penetration of the eyelid by the surgical instrument, an undesired and unnecessary means of surgery.

Therefore, Applicant submits that the combination Shahidi and LeBlanc et al. does not disclose or suggest the features recited in claim 10. Applicant respectfully requests that this rejection be withdrawn.

9. Examiner rejected claim 18 under 35 USC 103(a) as being unpatentable over Shahidi in view of Schachar (6,146,366).

10. Applicant respectfully disagrees with Examiner's rejection. Schachar describes an implant device to be placed in the eye,

> "the device includes a body adapted for association with the eye, having a shape prescribed to manipulate the retina of the eye to effectively augment the photoreceptor cells proximate the macula. The prescribed shape of the body of the device is that of a band, a segment, a partial band, a plate, or for that matter, any shape suitably adapted to perform the functions described or referenced herein to treat the effects of macular degeneration as well as other eye disorders. In point of fact, such body may likewise have any suitable geometric dimensions and physical shape, including circular, round, rectangular, triangular, quadrilateral, conical, or other like form, or suitable combination of two or more of the same." (Column 2, lines 55-67)

The invention described in Schachar is implanted into the eye, near the posterior region of the eye where the macula and retina are located, to alter the shape of the eye and redirect vision to areas of the retina unaffected by disease (See column 8, lines 1-31). While the

surface of the invention of Schachar may approximate the curve of the eye in that region, it still functions by deforming the interfacing tissues. Applicant's claimed design is directed towards a device that is applied to Schlemm's Canal and therefore the surface of the front or anterior region of the eye and is not implanted.

Furthermore, if the Schacher device were used, it would create an alteration of the shape of the eye that would apply undesired force and distortion during the guidance of the microcannula.

Also, it is unclear how Schachar could even be used with Sahidi, since Sahidi utilizes stored image data for image guidance and Schachar is meant to alter the shape of the eye. The altered shape of the eye would make the stored image data of Sahidi inaccurate and therefore of little use. When related to Applicant's invention, the inaccuracy of the data is especially problematic for microsurgery involving small structures such as Schlemm's Canal.

Therefore, Applicant submits that it would be counterproductive to combine the devices of Scachar and Sahidi. Further, even if the references were combined, the combination does not disclose or suggest the features recited in claim 18. Applicant respectfully requests that this rejection be withdrawn.

11. Examiner rejected claims 19, 27, 28, 29, 31 and 46 under 35 USC 103(a) as being unpatentable over Shahidi in view of Steen et al. (5,984,904).

12. Applicant respectfully disagrees with Examiner's rejection. Steen et al. describes

> "a sleeve for use with a surgical instrument having a slender cutting tip for removing the natural lens from an eye. The surgical sleeve includes a contoured interior surface which provides superior performance in reducing the frictional contact between the sleeve tip, and maximizes the effect of the fluid flow about the tip." (Column 1, lines 64-67, Column 2, lines 1-3)

13. Regarding claim 19, since Steen et al. is used intra-ocularly, it is totally immersed in fluid and does not require an additional coupling fluid for acoustic coupling of the ultrasound source to tissues. The contoured interior surface of the invention is described to provide improved mechanical (friction) and transport (characteristics). Applicant is unclear how the features of Steen et al. and Shahidi relate to maintaining placement of a coupling fluid during non-invasive ultrasound imaging as recited in claim 19.

    Since, the addition of the features of Steen et al. would not overcome the intrinsic deficiencies of Shahidi to function with soft, deformable tissues, as argued above with respect to claim 1, from which claims 19 depends, Applicant submits claim 19 is a novel and nonobvious over the combination of Shahidi and Steen et al. Applicant respectfully requests withdrawal of this rejection.

14. Regarding claims 27, 29 and 46, while Steen et al. describes a cutting tip to remove the natural lens of the eye, the properties of the lens is much different that the very tough sclera of the eye. The invention is described as "in use, sleeve 10 and tip 16 are inserted through a small incision in the eye" (Column 3, lines 34-35), not by penetration through the external tissues of the eye.

    Steen et al. does not described or suggest a microcannula designed to penetrate through the tissues of the sclera, to enter the cannalicular space and to allow advancement into Schlemm's Canal with minimal risk of trauma to adjacent tissues.

    Since, the addition of the features of Steen et al. would not overcome the intrinsic deficiencies of Shahidi to function with soft, deformable tissues, as argued above with respect to claim 1 and 45 (discussed below), from which claims 27, 29 and 46 depend, Applicant submits claims 27, 29 and 46 are novel and nonobvious over the combination of Shahidi and Steen et al. Applicant respectfully requests withdrawal of this rejection.

15. An embodiment of Steen et al., describes the contoured inner surface of the sleeve to have "protuberances are about 0.003 inches in height and out 0.010 inches in diameter along the

interior wall" (Column 3, lines 13-15). The dimensions of the protuberances are equal to 75 microns in height and 250 microns in diameter. Again, Schlemm's Canal of the eye is a vein-like tissue space approximately 150 microns in diameter. The surface features alone of the contoured inner sleeve of the invention described in Steen et al. are as large as Schlemm's canal. Although Steen et al. describes the use of a pliable outer sheath, neither Shahidi, nor Steen et al. has suggested or disclosed a device of a size and design usable to penetrate through the tissues of the sclera, to enter the cannalicular space and to allow advancement into Schlemm's Canal with minimal risk of trauma to adjacent tissues.

Therefore, Applicant submits claims 28 and 31 are novel and nonobvious over the combination of Shahidi and Steen et al. Applicant respectfully requests withdrawal of this rejection.

16. Examiner rejected claim 21 under 35 USC 103(a) as being unpatentable over Shahidi.

17. As mentioned above with regards to claims 1-4, 20, 24 and 32, there are design features of Shahidi, which would preclude its use in Schlemm's Canal. Therefore, there would be no reason to create the device of Shahidi in a size to fit within Schlemm's Canal. And even if Shahidi were created in a size capable of entry into Schlemm's Canal, it would not be suitable for such a use. Altering the size of Shahidi would not solve the problems with the inaccuracy of the stored data with respect to a soft tissue structure, image registration and device guidance into the structure, as discussed in further detail above.

    Therefore, Applicant submits that claim 21 is novel and nonobvious over Shahidi and respectfully requests withdrawal of this rejection.

18. Examiner rejected claims 22 and 23 under 35 USC 103(a) as being unpatentable over Shahidi in view of Imling et al. (6,203,499).

19. Applicant respectfully disagrees with Examiner's rejection. Imling et al. describes

> "a one piece needle guide is provided that consistently guides a needle into the insertion point of the body being examined such that the needle always enters the scan plane. The needle guide of the present invention also provides the user with the ability to freely maneuver the needle at multiple angles before and after insertion of the needle into the body being examined, while keeping the needle within the scan plane such that it is detected. The needle guide of the present invention is easy to clean, easy to operate, can be used with a wide range of needle sizes, and allows for the quick and easy release of the needle from the needle guide if required." (Column 3, lines 41-52)

From Examiner's statement, Applicant suggests a very key point may have been missed. Applicant is not just trying to get a needle tip to a general tissue area under imaging guidance, for example to sample tissue of a lesion for biopsy. Applicant's invention relates to introducing a surgical device into the vein-like tissue space of Schlemm's canal (described in our application as the Latin "sinus venosus sclerae") and advancing the device along the canal. This requires a near parallel approach to the canal long axis so that the surgical device does not simply transect or go through the canal. This is described in our application, for instance in the summary of the invention, which states "The microcannula is suitably dimensioned and shaped so as to be able to penetrate through the tissue of the sclera, to enter the canilicular space and to allow advancement into Schlemm's canal with minimal risk of trauma to adjacent tissues." In the case of the cited prior art, the target is not a vein-like structure nor does the needle need to be advanced within a vein-like tissue structure. As a result the angle of approach doesn't matter as long as the needle somehow intersects the tissue target. Whereas, in Applicant's claimed invention, the microcannula slidably advances into Schlemm's Canal.

Further, the invention of Imling et al. does not appear suited for guidance of a needle sized to access Schlemm's Canal. For example, "Needle guides are generally sized for one needle size, ranging from a large needle at 16 gauge to smaller needles at 22 gauge." (Column 3, lines 21-23) These needles sizes translate to 807 microns (22 gauge) and 1,625 microns outer diameter. It is difficult to envision placing these needles into an approximately 150

micron tissue space such as Schlemm's Canal. Also, the invention is described as "in any selected angle, needle 22 may freely move within slot 44 while it is inserted in the body being examined." (Column 5, lines 19-21) This indicates a lack of precision to place a needle or microcannula into a space as small as Schlemm's Canal.

Since, the addition of the features of Imling et al. would not overcome the intrinsic deficiencies of Shahidi to function with soft, deformable tissues, as argued above with respect to claim 20, from which claims 22 and 23 depend, Applicant submits claims 22 and 23 are novel and nonobvious over the combination of Shahidi and Steen et al. Applicant respectfully requests withdrawal of this rejection.

20. Examiner rejected claim 25 under 35 USC 103(a) as being unpatentable over Shahidi in view of Simon (4,883,053).

21. Applicant respectfully disagrees with Examiner's rejection. Simon describes

> "a self supporting angulator for precise percutaneous insertion of an object into the body of a subject is provided, this angulator comprising a base plate; at least one secondary member rotatably joined to the base plate at an angle substantially radial to the axis of the primary member, this secondary member being positionable adjacent to the primary member at a plurality of different angles of intersection; means for coupling the rotatable secondary member to the rotatable primary member at a desired angle of intersection; and means for holding the object to be inserted disposed upon at least one of the rotatable members." (Column 2, lines 37-49)

Again, we are not just trying to get a needle tip to a general tissue area under imaging guidance, for example to sample tissue of a lesion for biopsy. Our invention relates to introducing a surgical device into the vein-like tissue space of Schlemm's canal (described in our application as the Latin "sinus venosus sclerae") and advancing the device along the canal. This requires a near parallel approach to the canal long axis so that the surgical device does not simply transect or go through the canal. This is described in our application, which states "The microcannula is suitably dimensioned and shaped so as to be able to penetrate

through the tissue of the sclera, to enter the canalicular space and to allow advancement into Schlemm's canal with minimal risk of trauma to adjacent tissues." While the cited prior art describes a clip mechanism, the target is not a vein-like structure, nor does the needle need to be advanced within a vein-like tissue structure.

Also, Simon is described as

> "In its intended use with human or animal subjects, it is expected that the base plate 12 will be positioned on the skin of the subject at an insertion site overlying the tissue to be localized and/or examined. The center of the aperture 20 typically, will be positioned such that the needle point is situation directly over the planned site of skin penetration. The adhesive 38 will maintain the general position of the angulator device 10 on the skin of the subject without discomfort to the patient. The flexibility of the base plate material allows for movement through breathing or involuntary muscle contraction for the subject without loss of positioning for the angulator. Once the base plate has been attached to the skin surface, the L-shaped arms 82 and 62 are squeezed against the L-shaped arm section 72. The combination coupling bracket and needle holder 50 can now be moved along both arched members in any direction between 0 (degrees) and 180 (degrees) (preferably between 30 (degrees)-150(degrees)) relative to the skin surface and then secured into place." (Column 6, lines 48-66)

For use on the eye, an adhesive placed on the eye surface would be impractical and undesired due to trauma of sensitive eye tissues. Also, in Applicant's invention, where we are placing a microcannula to allow advancement into Schlemm's Canal, a needle should not be placed directly over the planned site of skin penetration as this would lead to penetration through the Canal. In Applicant's invention, the microcannula approaches the Canal in the plane of the Canal to allow tangential access.

Since, the addition of the features of Simon would not overcome the intrinsic deficiencies of Shahidi to function with soft, deformable tissues, as argued above with respect to claim 20, from which claim 25 depends, Applicant submits claim 25 is novel and nonobvious over the combination of Shahidi and Simon. Applicant respectfully requests that this rejection be withdrawn.

22. Examiner rejected claim 26 under 35 USC 103(a) as being unpatentable over Shahidi in view of Mohr, Jr. et al. (5,921,954).

23. Applicant respectfully disagrees with Examiner's rejection. Mohr Jr. et al. describes an invention that

> "relates to treating aneurysms and other body structures by applying a hardening/softening agent (such as RF energy) to a hardenable/softenable substance (such as collagen), along with associated steps. The invention provides a method and system for treating aneurysms and other body structures by delivering a hardenable substance (such as collagen) to the site of an aneurysm and applying a hardening means (such as RF energy) to that collagen or other hardenable substance. In a preferred embodiment, a catheter is disposed near the aneurysm and collagen is exuded into or near the aneurysm. RF energy is applied to the collagen, using either the same catheter or a second catheter, causing the collagen to harden and cover the second catheter, causing the collagen to harden and cover the weak region of the blood vessel wall, and providing a base onto which epithelial cells of the blood vessel may later grow so as to provide a new and strong blood vessel wall." (Column 1, lines 66-67, column 2, lines 1-14)

While Mohr, Jr. et al. describes the use of a catheter with a curved needle-like shape adapted to a surface curvature of an eye, it does not describe the use of such a catheter for accessing a small curved tissue space such as Schlemm's Canal of the eye. It is unclear how the use of a catheter with a curved needle-like shape as described in Mohr, Jr. et al. would overcome the intrinsic limitation of the primary cited prior art, Shahidi to function with soft, deformable tissues.

Therefore, Applicant submits that the combination Shahidi and Mohr, Jr. et al. does not disclose or suggest the features recited in claim 26. Applicant respectfully requests that this rejection be withdrawn.

24. Examiner rejected claims 32-34, 38 and 45 under 35 USC 103(a) as being unpatentable over Shahidi in view of Lynch et al. (6,524,275).

25. Applicant respectfully disagrees with Examiner's rejection. Lynch et al. describes

> "a novel inflatable catheter device and an associated method for the surgical correction of glaucoma in which the inventive device is placed within Schlemm's canal and the inflatable element of the device is expanded to temporarily stretch and expand the lumen of the canal. At that point, the inflatable element may be used to temporarily occlude outflow through the canal, while physiologic material is injected through another lumen of the device, thereby distending the canal and expanding areas of stenosis within the canal. The inflated element may be decompressed and removed after the desired expansion is achieved, or the device may be extracted with the inflatable component expanded, to further mechanically dilate the passageway within Schlemm's canal."
>
> "The present invention may also be employed to inject various medications directly within Schlemm's canal. Such medications may include, but are not limited to, antifibrotics, antibiotics, and other medications which may have direct effects within the internal structures of Schlemm's canal, the trabecular meshwork, and other tissues of the eye."
>
> "The present invention may also be employed to deploy various stents or shunts directly within Schlemm's canal to help maintain patency within the canal following removal of the inflatable device."

While Lynch et al. describes the use of an inflatable device placed within Schlemm's canal, it does not describe means for placing the device within the Canal by minimally invasive means. "The surgical procedure necessary to insert the device requires an approach through a fornix-based conjunctival flap." (Column 7, lines 53-55.) It is unclear how the use of Lynch et al. would overcome the intrinsic limitation of Shahidi to function with soft, deformable tissues, as discussed above.

In Applicant's claimed invention, we describe injection of materials, inflatable balloons and implants into Schlemm's canal. This would be very difficult, if the surgical device or microcannula is not placed within the canal and advanced within the canal for at least a short distance. For example when injecting into a vein with a needle and syringe, a physician does not simply place the tip of the needle into the blood vessel at an acute angle. The needle is place somewhat in alignment with the vessel and advanced for at least a short distance within the vein so the injectate may be induce to flow into the vein. Shahidi does not describe

means to access and advance a microcannula along a tissue space such as Schlemm's Canal, and Lynch et al. does not provide any suggestion to overcome this limitation.

Therefore, Applicant submits that claims 32-34, 38 and 45 are novel and nonobvious over the combination of Shahidi and Lynch et al. and respectfully requests that this rejection be withdrawn.

26. Examiner rejected claims 39 and 42 under 35 USC 103(a) as being unpatentable over Shahidi in view of Lafont et al. (5,957,975).

27. Applicant respectfully disagrees with Examiner's rejection. Lafont et al. describes

> "a biodegradable polymeric stent designed to prevent the chronic constriction and to allow physiologic enlargement of the lumen of a blood vessel at the site of the original stenotic lesion during the initial three to six months following deployment of the stent. The stent has a programmed pattern of in vivo degradation. When deployed, the stent comprises at least one substantially cylindrical element having two open ends and a plurality of regions circumferentially spaced around the cylindrical element and extending from one open end to the other open end of the cylindrical element. Each of the regions is configured or designed to have a desired in vivo lifetime. At least one of the regions is designed to have a shorter in vivo lifetime than the other region or regions. This means that the region having the shorter in vivo lifetime degrades sooner after deployment than the regions having a longer in vivo lifetime. Thus, when stents designed in accordance with the present invention are deployed within the lumen of a vessel of a patient, the cylindrical element acquires one or more fissures which extend from one open end of the cylindrical element to the other open end of the cylindrical element within a desired, predetermined period of time after the stent is deployed in the patient. It has been determined that such fragmentation within a predetermined period of time after deployment allows for enlargement of the lumen of the vessel via the process of arterial remodeling." (Column 2, line 52 – Column 3, line 11)

The ultra structure and anatomy of Schlemm's Canal differs significantly from arteries, lacking a tunica media and tunica adventitia associated with arterial remodeling. Therefore, it would not be obvious to one of ordinary skill in the art that Schlemm's Canal of the eye

could undergo arterial remodeling, the biological mechanism involved of the invention described in Lafont et al.

As discussed above, Applicant's application describes injection of materials, inflatable balloons and implants into Schlemm's canal, including an expandable stent and an expandable stent comprised of a biodegradable material through minimally invasive means. This would be very difficult if the surgical device or microcannula is not placed within the canal and advanced within the canal for at least a short distance. For example, when injecting into a vein with a needle and syringe, a physician does not simply place the tip of the needle into the blood vessel at an acute angle. The needle is place somewhat in alignment with the vessel and advanced for at least a short distance within the vein so the injectate may be induce to flow into the vein.

Since, the addition of the features of Lafont would not overcome the intrinsic deficiencies of Shahidi to function with soft, deformable tissues, as argued above with respect to claim 38, from which claims 39 and 42 depend, Applicant submits claims 39 and 42 are novel and nonobvious over the combination of Shahidi and Lafont. Applicant respectfully requests that this rejection be withdrawn.

28. In summary, the prior art cited does not describe means to introduce and advance a surgical device or microcannula into a tissue space (cannulation) such as Schlemm's Canal, to advance the microcannula at high precision or means to couple advancement of the surgical tool under control by the imaging system.

CONCLUSION

For all the reasons above, Applicant submits that the claims all define novel subject matter that is nonobvious. Therefore, allowance of these claims is submitted to be proper and is respectfully requested.

Applicant invites the Examiner to contact Applicant's representative as listed below for a telephonic interview if so doing would expedite the prosecution of the application.

Very respectfully submitted,

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Carol D. Titus